Premarket Notification [510(k)] Summary

JUL 0 3 2013

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92

The assigned 510(k) number is : k123171

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Date Prepared: 02nd July, 2013

A. Device Names:

The following reagent, controls & calibrators are for use in conjunction with the ABX PENTRA 400 instrument, cleared to market under K052007.

REAGENTS :

Trade/Proprietary Name:	**ABX PENTRA CALCIUM AS CP**
Common or Usual Name:	Calcium Arsenazo
Device Class	Class II
Classification Name:	§862.1145 : Calcium test system
Product Code:	CJY: Azo Dye, Calcium

CALIBRATORS:

Trade/Proprietary Name:	**ABX PENTRA Multical** (Already cleared to market under K052007)
Common or Usual Name:	Multical
Device Class	Class II
Classification Name:	§862.1150 : Calibrator
Product Code:	JIX ; Calibrator, Multi-Analyte Mixture

CONTROLS :

Trade/Proprietary Name:	**ABX PENTRA N Control** (Already cleared to market under K052007)
Common or Usual Name:	N Control
Device Class	Class I
Classification Name:	§862.1660 : Quality control material (assayed)
Product Code:	JJY ; Multi-Analyte Controls, All Kinds (Assayed)

Trade/Proprietary Name:	**ABX PENTRA P Control** (Already cleared to market under K052007)
Common or Usual Name:	P Control
Device Class	Class I
Classification Name:	§862.1660 : Quality control material (assayed)
Product Code:	JJY ; Multi-Analyte Controls, All Kinds (assayed)

Trade/Proprietary Name:	**ABX PENTRA Urine Control L/H** (Already cleared to market under K070249)
Common or Usual Name:	Urine control
Device Class	Class I
Classification Name:	§862.1660 : Quality control material (assayed)
Product Code:	JJY ; Multi-Analyte Controls, All Kinds (Assayed)

B. Substantial Equivalence:

The data and information supplied in this submission demonstrates substantial equivalence to their respective predicate devices:

Submission device	Substantially equivalent Predicate device
ABX Pentra Calcium AS CP	K061575
ABX Pentra Multical	K052007
ABX Pentra N Control	K052007
ABX Pentra P Control	K052007
ABX Pentra Urine Control L/H	K070249

1. Comparison of new device (**ABX Pentra Calcium AS CP**) with the predicate device (**Olympus Calcium Arsenazo reagent**):

   - **Similarities :**

	Predicate device (K061575):	**New Device :**
Device Name	**Olympus Calcium Arsenazo reagent**	**ABX Pentra Calcium AS CP**
Indications for use	Olympus Calcium Arsenazo reagent is a diagnostic reagent for quantitative in vitro determination of calcium in human serum, plasma and urine by colorimetry. Measurement of calcium is used in the diagnosis and treatment of parathyroid disease, a variety of bone diseases, chronic renal disease and tetany (intermittent muscular contractions or spasms).	Identical

Analytes	Calcium	Identical
Method	Calcium ions (Ca2+) react with Arsenazo III (2,2'-[1,8-Dihydroxy-3,6-disulphonaphthylene-2,7-bisazo]- bisbenzenearsonic acid) to form an intense purple coloured complex. The absorbance of the Ca-Arsenazo III complex is measured bichromatically at 660/700 nm. The resulting increase in absorbance of the reaction mixture is directly proportional to the calcium concentration in the sample.	Identical
Specimen	Serum, plasma and urine	Identical
Closed reagent stability	Until the expiration date printed on the label when stored at 2-8°C	Identical
Format	Liquid	Identical

- **Differences :**

	Predicate device (K061575):	**Device :**
Device Name	**Olympus Calcium Arsenazo reagent**	**ABX Pentra Calcium AS CP**
Manufactured by	Olympus Corp /Beckman Coulter	HORIBA ABX SAS, France
Instrument	Clinical chemistry analyzer	ABX PENTRA 400
Component reagent matrices	Mono reagent bottle, ready to use. Final reactive ingredient: Arsenazo III	Mono reagent cassette, ready to use. Final reactive ingredient: Identical
Label	-	Horiba Medical specific label
Notice	Beckman Coulter specific notice	Horiba Medical specific notice
Packaging	Mono reagent bottle REAGENT: 4 x15 ml	Mono-reagent cassette : REAGENT : 1x79 ml
Controls	Commercially available quality control material (not included): Controls Cat. No.ODC0003 and ODC0004 for serum/plasma. Biorad Liquichek Urine Chemistry Controls Cat. No. 397 and 398 for urine.	Recommended quality control material (not included): ABX Pentra N Control and ABX Pentra P Control for serum /plasma. ABX Pentra Urine Control L/H for urine.
Calibrators	Commercially available calibrator (not included): System Calibrator Cat. No. 66300 for serum/plasma application and Urine Calibrator Cat. No. ODC0025 for urine	Recommended calibration material (not included): ABX Pentra Multical
Open Reagent stability	Once open, reagent stored on board the instrument is stable for 90 days.	Once opened, the reagent cassette placed in the instrument (refrigerated

		compartiment at 2-8°C) is stable for 60 days

2. Comparison of new device (ABX Pentra MULTICAL) with the predicate device (ABX Pentra MULTICAL already cleared to market under K052007):

The ABX Pentra MULTICAL was previously described and cleared by the FDA under K052007 and the following submissions K062737, K060205, K062180, K060854, K060434, K072115, K110137, K110530.

However we have added it in this submission, as it is used in combination with a parameter. The only difference between the previously cleared calibrator and the ones included in this submission is the parameter calibrated submitted to the FDA.

- **Similarities :**

	Predicate device (K052007):	**Device :**
Device Name	ABX Pentra MULTICAL	ABX Pentra MULTICAL
Manufactured by	Roche	Unchanged
Commercialized by	HORIBA ABX SAS, France	Unchanged
Instrument	ABX PENTRA 400	Unchanged
Method :	Calibration of HORIBA Medical methods on clinical chemistry analyzers	Unchanged
Component reagent matrices	-Vial (lyophilizate) -Human serum with chemical additives and tissue extracts of human and animal origin	Unchanged
Biological additives	ALT (GPT), AST (GOT), Albumin, Aldolase, Alkaline phosphatase, Amylase total, Pancreatic Amylase, Cholesterol, Cholinesterase, Creatine Kinase, Gamma-GT, GLDH, LD (LDH), Lipase, Acid phosphatase, Total proteins	Unchanged
Format	Lyophilizate (to reconstitute with distilled/deionised water – not provided)	Unchanged
Labels	Horiba Medical specific label	Unchanged
Notice	Horiba Medical specific notice	Unchanged
Packaging	Kit composed of : 10 x bottle, each with lyophilizate for 3 ml calibrator	Unchanged
Performance data : Calibration values	- Determined using parameter-specific methods (mentioned in the annex) under strictly standardized conditions on HORIBA Medical	Unchanged

	analyzers using HORIBA Medical system reagents and HORIBA Medical master calibrator - The calibration value specified is the median of the values obtained - The assigned values are indicated in the annex enclosed in the kit - The values are lot-specific.	
Performance data : Closed stability	24 months at 2-8°C	Unchanged
Performance data : Components stability after reconstitution of the calibrator**	At 15 to 25°C : 8 hours At 2 to 8°C: 2 days At –25°C to –15°C: 2 weeks (when frozen once) **Exceptions: Stability of Direct Bilirubin At 15 to 25°C: 3 hours At 2 to 8°C: 8 hours At –25°C to –15°C: 2 weeks (when frozen once) Stability of Total Bilirubin At 15 to 25°C: 6 hours At 2 to 8°C: 1 day At –25°C to –15°C: 2 weeks (when frozen once)	Unchanged

- **Differences :**

Device (K052007):	Device:	
Device Name	ABX Pentra MULTICAL	ABX Pentra MULTICAL
Calibrated molecules	The exact calibrator values are given in the enclosed annex	Updated to include new application values for new arsenazo calcium
Calibrated molecules: ALP, ALT, Amylase, AST, Creatine kinase, GGT, Lipase, Albumin, Direct Bilirubin, Total Bilirubin, Calcium, Cholesterol, Creatinine 120, Glucose HK, Glucose PAP, Iron, Lactic Acid, Magnesium, Phosphorus, Total Protein, Total protein 100, Triglyverides, Urea/BUN, Uric acid, Enzymatic Creatinine, **New Arsenazo Calcium**	Applications cleared K060205 CLIA K062180 K06318 K062737 CLIA CLIA K060434 K060325 K060325 K060205 K060854 K072115 - K062007 K062007 K060505 CLIA K060205 K060205 K060434 K072115 K060854 K060205 K060205 K110137 K110530	- **New Arsenazo Calcium** Application not cleared (in this submission)
Value sheet/Annex	Horiba Medical specific annex	New Horiba Medical specific annex

3. Comparison of new device (ABX Pentra N CONTROL) with the predicate device (ABX Pentra N CONTROL already cleared to market under K052007):

The ABX Pentra N CONTROL was previously described and cleared by the FDA under K052007 and the following submissions K062737, K060205, K060318, K060325, K062180, K060854, K060434, K072115, K110137, K110530.

However we have added it in this submission, as it is used in combination with a parameter. The only difference between the previously cleared control and the ones included in this submission is the parameter controlled submitted to the FDA.

- **Similarities :**

	Predicate device (K052007):	**Device :**
Device Name	**ABX Pentra N Control**	**ABX Pentra N Control**
Manufactured by	Roche	Unchanged
Commercialized by	HORIBA ABX SAS, France	Unchanged
Instrument	ABX PENTRA 400	Unchanged
Method :	- Quality control by monitoring accuracy and precision for the quantitative methods as specified in the enclosed value sheet - Concentrations and activities are mostly in the normal or near-normal range	Unchanged
Component reagent matrices	-Vial (lyophilizate) -Human serum with chemical additives and tissue extracts of human and animal origin	Unchanged
Biological additives	ALT (GPT), AST (GOT), Albumin, Aldolase, Alkaline phosphatase, Amylase total, Pancreatic Amylase, Cholesterol, Cholinesterase, Creatine Kinase, Gamma-GT, GLDH, LD (LDH), Lipase, Acid phosphatase, Total proteins	Unchanged
Format	Lyophilizate (to reconstitute with distilled/deionised water – not provided)	Unchanged
Labels	Horiba Medical specific label	Unchanged
Notice	Horiba Medical specific notice	Unchanged
Packaging	Kit composed of : 10 x bottle, each with lyophilizate for 5 ml control	Unchanged
Performance data : Theoretical values and confidence intervals	- The theoretical value specified is the median of the values obtained, the confidence interval equals the theoretical value ± 3SD (SD = Standard	Unchanged

	Deviation) - The assigned values are indicated in the annex enclosed in the kit. -The values are lot-specific.	
Performance data : Closed stability	30 months at 2-8°C	Unchanged
Components stability after reconstitution of the control**	At 15-25°C :12 hours At 2-8°C : 5 days At (-15°C) - (-25°C) : 4 weeks (when frozen once) **Exceptions: Stability of Total Bilirubin At 15-25°C : 8 hours At 2 - 8°C : 24 hours At (-15°C)- (-25°C) :2 weeks (when frozen once) Stability of Direct Bilirubin At 15 - 25°C : 4hours At 2 - 8°C : 8 hours At (-15°C) - (-25°C) :2 weeks (when frozen once)	Unchanged

- **Differences :**

	Predicate device (K052007):	**Device :**
Device Name	**ABX Pentra N Control**	**ABX Pentra N Control**
Controlled molecules	The exact control values are given in the enclosed annex	Updated to include new application values for new arsenazo calcium
Controlled molecules :	Applications cleared :	Application not cleared under this submission:
ALP, ALT, Amylase, AST, Creatine kinase, GGT, Lipase, Albumin, Direct Bilirubin, Total Bilirubin, Calcium, Chloride, Cholesterol, HDL, LDL, Creatinine 120, Glucose HK, Glucose PAP, Iron, Lactic Acid, Magnesium, Phosphorus, Potassium, Sodium, Total Protein, Total Protein 100, Triglycerides, Urea/BUN, Uric acid, Enzymatic Creatinine, **new arsenazo calcium**	K060205, CLIA, K062180, K06318, K062737, CLIA, CLIA, K060434, K060325, K060325, K060205, K052007, K060854, K060854, K060854, K072115,K052007, K052007, K060205, CLIA, K060205, K060205, K052007, K052007, K060434, K072115, K060854, K060205, K060205, K110137 K110530, - .	**- New arsenazo calcium** Application not cleared (in this submission)
Value sheet / Annex	Horiba Medical specific annex	New Horiba Medical

		specific annex

4. Comparison of new device (ABX Pentra P CONTROL) with the predicate device (ABX Pentra P CONTROL already cleared to market under K052007):

The ABX Pentra P CONTROL was previously described and cleared by the FDA under K052007 and the following submissions K062737, K060205, K060318, K060325, K062180, K060854, K060434, K072115, K110137, K110530.

However we have added it in this submission, as it is used in combination with a parameter. The only difference between the previously cleared control and the ones included in this submission is the parameter controlled submitted to the FDA.

- **Similarities :**

	Predicate device (K052007):	**Device :**
Device Name	**ABX Pentra P Control**	**ABX Pentra P Control**
Manufactured by	Roche	Unchanged
Commercialized by	HORIBA ABX SAS, France	Unchanged
Instrument	ABX PENTRA 400	Unchanged
Method :	Quality control by monitoring accuracy and precision for the quantitative methods as specified in the enclosed value sheet Concentrations and activities are mostly in the normal or near-normal range	Unchanged
Component reagent matrices	Vial (lyophilizate) Human serum with chemical additives and tissue extracts of human and animal origin	Unchanged
Biological additives	ALT (GPT), AST (GOT), Albumin, Aldolase, Alkaline phosphatase, Amylase total, Amylase Pancreatic, Cholesterol, Cholinesterase, Creatine Kinase, Gamma-GT, GLDH, LD (LDH), Lipase, Acid phosphatase, Total proteins	Unchanged
Format	Lyophilizate (to reconstitute with distilled/deionised water – not provided)	Unchanged
Labels	Horiba Medical specific label	Unchanged
Notice	Horiba Medical specific notice	Unchanged
Packaging	Kit composed of : 10 x bottle, each with lyophilizate for 5 ml control	Unchanged
Performance data : Theoretical values and	- The theoretical value specified is the median of the values obtained, the confidence interval equals the	Unchanged

confidence intervals	theoretical value ± 3SD (SD = Standard Deviation) - The assigned values are indicated in the annex enclosed in the kit. -The values are lot-specific.	
Performance data : Closed stability	30 months at 2-8°C.	Unchanged
Performance data : Components stability after reconstitution of the control**	At 15-25°C :12 hours At 2-8°C : 5 days At (-15°C) - (-25°C) : 1 month (when frozen once) **Exceptions: Stability of Total Bilirubin At 15-25°C : 8 hours At 2 - 8°C : 24 hours At (-15°C)- (-25°C) :2 weeks (when frozen once) Stability of Direct Bilirubin At 15 - 25°C : 4hours At 2 - 8°C : 8 hours At (-15°C) - (-25°C) :2 weeks (when frozen once)	Unchanged

- **Differences :**

	Predicate device (K052007):	**Device :**
Device Name	**ABX Pentra P Control**	**ABX Pentra P Control**
Controlled molecules	The exact control values are given in the enclosed annex	Updated to include new application values for new arsenazo calcium
Controlled molecules :	Applications cleared :	Application not cleared under this submission:
ALP, ALT, Amylase, AST, Creatine kinase, GGT, Lipase, Albumin, Direct Bilirubin, Total Bilirubin, Calcium, Chloride, Cholesterol, HDL, LDL, Creatinine 120, Glucose HK, Glucose PAP, Iron, Lactic Acid, Magnesium, Phosphorus, Potassium, Sodium, Total Protein, Total Protein 100, Triglycerides, Urea/BUN, Uric acid, Enzymatic Creatinine, **New arsenazo calcium**	K060205, CLIA, K062180, K06318, K062737, CLIA, CLIA, K060434, K060325, K060325, K060205, K052007, K060854, K060854, K060854, K072115,K052007, K052007, K060205, CLIA, K060205, K060205, K052007, K052007, K060434, K072115, K060854, K060205, K060205, K110137 K110530	**New arsenazo calcium** Application not cleared (in this submission)

Value sheet / Annex	Horiba Medical specific annex	New Horiba Medical specific annex

5. Comparison of new device (ABX Pentra URINE CONTROL L/H) with the predicate device (ABX Pentra URINE CONTROL L/H already cleared to market under K070249):

The ABX Pentra URINE CONTROL L/H was previously described and cleared by the FDA under K070249 and the following submission K072115, K110137, K110530.
However we have added it in this submission, as it is used in combination with a parameter. The only difference between the previously cleared control and the ones included in this submission is the parameter controlled submitted to the FDA.

- **Similarities :**

	Predicate device (K070249):	**Device :**
Device Name	**ABX Pentra Urine Control L/H**	**ABX Pentra Urine Control L/H**
Manufactured by	Biorad	Unchanged
Commercialized by	HORIBA ABX SAS, France	Unchanged
Instrument	ABX PENTRA 400	Unchanged
Method :	Quality control by monitoring accuracy and precision for the quantitative methods as specified in the enclosed value sheet.	Unchanged
Component reagent matrices	Vial (liquid) 2 levels : Low / High Human urine with added constituents of human and animal origin, chemicals, preservatives and stabilizers.	Unchanged
Format	Liquid, ready to use	Unchanged
Labels	Horiba Medical specific label	Unchanged
Notice	Horiba Medical specific notice	Unchanged
Packaging	Kit composed of : 1 x 10 ml Low Control 1 x 10 ml High Control	Unchanged
Performance data : Theoretical values and confidence intervals	- The assigned values are determined by calculating the median value obtained from multiple determinations. - The assigned values for both Low and High controls are lot specific - The assigned values and precise confidence interval are indicated in the annex enclosed in the	Unchanged

	kit	
Closed stability	2 years at 2-8°C	Unchanged
Open stability	30 days at 2-8°C	Unchanged

- **Differences :**

	Predicate device (K070249):	**Device :**
Device Name	**ABX Pentra Urine Control L/H**	**ABX Pentra Urine Control L/H**
Controlled molecules	The exact control values are given in the enclosed annex	Updated to include new application values for new arsenazo calcium
Controlled molecules :	Applications cleared :	Application not cleared under this submission:
Amylase, Calcium, Phosphorus, Glucose HK, Urea/BUN, Uric Acid, Total Proteins (Urinary), Creatinine 120, Enzymatic Creatinine, **New Arsenazo Calcium**	K070249, K070249, K070249, K070146, K070146, K070146, K070146, K072115, K110137 K110530, -	**New Arsenazo Calcium** Application not cleared (in this submission)
Value sheet / Annex	Horiba Medical specific annex	New Horiba Medical specific annex

C. Description:

All the reagent, controls and calibrator included in this submission are for use on the **ABX PENTRA 400** (K052007), which is a discrete photometric benchtop clinical chemistry analyzer.

The **ABX Pentra Calcium AS CP** is an in vitro diagnostic assay for the quantitative in vitro determination of calcium in human serum, plasma and urine based on colourimetric method. It is composed of a monoreagent cassette (79 mL). The reagent is chemical solution with additives.

The **ABX PENTRA Multical** is a lyophilized human serum calibrator with chemical additives and materials of biological origin. The assigned values of the calibrator components are given in the enclosed annex, ensuring optimal calibration of the appropriate HORIBA ABX SAS methods on the ABX PENTRA 400 analyzer.
This calibrator is provided in ten vials of 3 ml.

The **ABX PENTRA N Control** and **ABX PENTRA P Control** are quality control products consisting of lyophilized human serum with chemical additives and materials of biological origin added as required to obtain given component levels. The assigned values of the control components are given in the enclosed annexes, ensuring control of the appropriate HORIBA

ABX SAS methods on the ABX PENTRA 400 analyzer. Each control is provided in ten vials of 5 ml.

The **ABX PENTRA Urine Control L/H** is a two-level (Low and High) quality control consisting of liquid solutions prepared from human urine with chemical additives and materials of biological origin added as required to obtain given component levels. The assigned values of the control components are given in the enclosed annex, ensuring control of the appropriate HORIBA ABX SAS methods on the ABX PENTRA 400 analyzer. Each control level is provided in one vial of 10 ml.

D. Intended Use:

The reagent in this submission is intended for use on the **ABX PENTRA 400**.

The controls and calibrator are intended for use in association with the above reagent on the ABX PENTRA 400.

Indications for use:

ABX Pentra Calcium AS CP reagent, with associated calibrator and controls, is a diagnostic reagent for quantitative in vitro determination of calcium in human serum, plasma and urine based on a colourimetric method, using the ABX Pentra 400 Clinical Chemistry analyzer. Measurement of calcium is used in the diagnosis and treatment of parathyroid disease, a variety of bone diseases, chronic renal disease and tetany (intermittent muscular contractions or spasms).

The ABX PENTRA Multical is a calibrator for use in the calibration of quantitative Horiba Medical methods on Horiba Medical clinical chemistry analyzers.
The ABX PENTRA N Control is for use in quality control by monitoring accuracy and precision of Horiba Medical methods on Horiba Medical clinical chemistry analyzers.
The ABX PENTRA P Control is for use in quality control by monitoring accuracy and precision of Horiba Medical methods on Horiba Medical clinical chemistry analyzers.
The ABX PENTRA Urine Control L/H is for use in quality control by monitoring accuracy and precision of Horiba Medical methods on Horiba Medical clinical chemistry analyzers.

E. Discussion of nonclinical tests submitted:

All the performance studies were conducted using the ABX Pentra 400 clinical chemistry analyzer.

1. Detection limit

   The detection limits are determined according to CLSI (NCCLS), EP17-A protocol: *Protocols for determination of limits of detection and limits of quantitation. Approved Guideline, CLSI (NCCLS) document EP17-A (2004) 24 (34).*
   Serum/Plasma : 0.28 mg/dl
   Urine : 0.23 mg/dl

2. Limit of quantitation

   The limits of quantitation are determined according to CLSI (NCCLS), EP17-A protocol: *Protocols for determination of limits of detection and limits of quantitation. Approved Guideline, CLSI (NCCLS) document EP17-A (2004) 24 (34).*
   Serum/Plasma : 1.54 mg/dl
   Urine : 0.64 mg/dl

3. Repeatability (within-run precision)

   3 specimens of low, medium and high concentration and 2 controls are tested 20 times according to the recommendations found in the Valtec protocol : *Vassault A, Grafmeyer D, Naudin C et al. Protocole de validation de techniques (document B). Ann. Biol. Clin. (1986) 44: 686-745.*

   For serum/plasma

	Mean value (mg/dl)	CV%
Control specimen 1	8.39	0.49
Control specimen 2	12.53	0.37
Specimen 1	6.91	0.71
Specimen 2	9.18	0.40
Specimen 3	13.15	0.43

   For urine

	Mean value (mg/dl)	CV%
Control specimen 1	7.27	0.62
Control specimen 2	10.86	0.76
Specimen 1	7.73	0.46
Specimen 2	10.50	0.56
Specimen 3	14.50	0.37

4. Reproductibility (total precision)

   3 specimens of low, medium and high levels and 2 controls are tested in duplicate for 20 days (2 series per day) according to the recommendations found in the CLSI (NCCLS),

EP5-A2 protocol : *Evaluation of Precision Performance of Quantitative Measurement Method. Approved Guideline, CLSI (NCCLS) document EP5-A2 (2004) 24 (25).*

For serum/plasma

	Mean value (mg/dl)	CV%
Control specimen 1	8.72	1.44
Control specimen 2	13.02	1.49
Specimen 1	7.03	1.56
Specimen 2	9.47	1.54
Specimen 3	12.93	1.54

For urine

	Mean value (mg/dl)	CV%
Control specimen 1	7.28	1.45
Control specimen 2	10.71	1.50
Specimen 1	7.70	1.57
Specimen 2	10.27	1.57
Specimen 3	14.21	1.56

5. Measuring range

The assay confirmed a measuring range from 4.0 mg/dl – 18.05 mg/dl (for serum/plasma) and 0.64 mg/dl – 18.05 mg/dl (for urine), with an automatic post-dilution up to 54.15 mg/dl.
According to the recommendations found in the CLSI (NCCLS), EP6-A protocol : *Evaluation of the Linearity of Quantitative Analytical Methods. Approved Guideline, CLSI (NCCLS) document EP6-A (2003) 23 (16),* the reagent linearity for serum/plasma and urine has been assessed up to 18.05 mg/dl, and with automatic post-dilution : 54.15 mg/dl.

6. Method comparison

According to the recommendations found in the CLSI (NCCLS), EP9-A2 protocol: *Method Comparison and Bias Estimation Using Patient Samples. Approved Guideline, 2nd ed., CLSI (NCCLS) document EP9-A2 (2002) 22 (19),* patient samples (n=145 for serum/plasma ; n=143 for urine) are correlated with a commercial reagent taken as reference.

Values ranged from 4.17 mg/dl to 15.76 mg/dl for serum/plasma and 0.64 mg/dl to 17.80 mg/dl for urine.

The equations for the allometric line obtained using Passing- Bablock regression procedure: *Passing H, Bablock W. A new biometrical procedure for testing the equality of measurements from two different analytical methods. J. Clin. Chem. Clin. Biochem. (1983) 21: 709-20.,* are:
For serum/plasma: $Y = 1.00 x + 0.04$ (mg/dl) with $r^2 = 0.9903$
For urine: $Y = 0.98 x - 0.03$ (mg/dl) with $r^2 = 0.993$

7. Matrix comparison study

A matrix comparison study between serum and lithium plasma samples was performed using 32 paired serum and lithium plasma samples, ranging in calcium concentration from 4.0 mg/dL to 17.5 mg/dL (3 samples were altered). Each sample was tested in singulate using the ABX Pentra Calcium AS CP assay reagent. Linear regression analysis of the plot of serum (x-axis) and lithium plasma (y-axis) samples showed the following relationships between the matrix types: $y = 1.006x - 0.0022$, $r^2 = 0.996$

8. Calibration stability

The reagent is calibrated on Day 0. The calibration stability is checked by testing 2 control specimens.
The calibration stability is 10 days for serum/plasma and urine.
A recalibration is recommended when reagent lots change, and when quality control results fall outside the range established.

9. Reagent stability

Closed stability: 24 months at 2-8°C
On-board stability: 60 days at 2-8°C

F. CALIBRATOR

ABX PENTRA Multical:		
Analytes	Already cleared (K052007, K060205, K060318, K060325, K060854, K062180, K062737, K060434, K072115, K110137, K110530)	Included in this submission
Alkaline phosphatase	√	√
Alanine aminotransferase	√	√
Amylase	√	√
Aspartate aminotransferase	√	√
Creatine kinase	√	√
GGT	√	√
LDH	√	√
Lipase	√	√
Albumin	√	√
Direct Bilirubin	√	√
Total Bilirubin	√	√
Calcium	√	√
New Calcium AS		√
Cholesterol	√	√
Creatinine 120	√	√
Enzymatic Creatinine CP	√	√

ABX PENTRA Multical:		
Glucose HK	√	√
Glucose PAP	√	√
Iron	√	√
Lactic acid	√	√
Magnesium	√	√
Phosphorus	√	√
Total Protein	√	√
Total Protein 100	√	√
Triglycerides	√	√
Urea / Blood Urea Nitrogen	√	√
Uric acid	√	√
Format	Lyophilized human serum with chemical additives and materials of biological origin	
Stability	Closed stability: 24 months at 2-8°C Open stability: Once opened, the calibrator components** are stable for : 8 hours at 15°C to 25°C 2 days at 2°C to 8°C 2 weeks at –25°C to –15°C **Exceptions Direct Bilirubin 3 hours at 15°C to 25°C 8 hours at 2°C to 8°C 2 weeks at –25°C to –15°C Total Bilirubin 6 hours at 15°C to 25°C 1 day at 2°C to 8°C 2 weeks at –25°C to –15°C	

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G. CONTROLS

ABX PENTRA N Control:		
Analytes	Already cleared (K052007, K060205, K060318, K060325, K060854, K062180, K062737, K060434, K072115, K110137, K110530)	Included in this submission
Alkaline phosphatase	√	√
Alanine aminotransferase	√	√
Amylase	√	√
Aspartate aminotransferase	√	√
Creatine kinase	√	√
GGT	√	√
LDH	√	√
Lipase	√	√

ABX PENTRA N Control:		
Albumin	√	√
Direct Bilirubin	√	√
Total Bilirubin	√	√
Calcium	√	√
New Calcium AS		√
Chloride	√	√
Cholesterol	√	√
HDL	√	√
LDL	√	√
Creatinine 120	√	√
Enzymatic Creatinine CP	√	√
Glucose HK	√	√
Glucose PAP	√	√
Iron	√	√
Lactic acid	√	√
Magnesium	√	√
Phosphorus	√	√
Potassium	√	√
Sodium	√	√
Total Protein	√	√
Total Protein 100	√	√
Triglycerides	√	√
Urea / Blood Urea Nitrogen	√	√
Uric acid	√	√

.../...

Format	Lyophilized human serum with chemical additives and materials of biological origin
Stability	Closed stability: 30 months at 2-8°C Open stability: Once opened, the control components** are stable for : 12 hours at 15°C to 25°C 5 days at 2°C to 8°C 1 month at –25°C to –15°C **Exceptions Direct Bilirubin 4 hours at 15°C to 25°C 8 hours at 2°C to 8°C 2 weeks at –25°C to –15°C Total Bilirubin 8 hours at 15°C to 25°C 1 day at 2°C to 8°C 2 weeks at –25°C to –15°C

ABX PENTRA P Control:		
Analytes	Already cleared (K052007, K060205, K060318, K060325, K060854, K062180, K062737, K060434, K072115, K110137, K110530)	Included in this submission
Alkaline phosphatase	√	√
Alanine aminotransferase	√	√
Amylase	√	√
Aspartate aminotransferase	√	√
Creatine kinase	√	√
GGT	√	√
LDH	√	√
Lipase	√	√
Albumin	√	√
Direct Bilirubin	√	√
Total Bilirubin	√	√
Calcium	√	√
New Calcium AS		√
Chloride	√	√
Cholesterol	√	√
HDL	√	√
LDL	√	√
Creatinine 120	√	√
Enzymatic Creatinine CP	√	√
Glucose HK	√	√
Glucose PAP	√	√
Iron	√	√
Lactic acid	√	√
Magnesium	√	√
Phosphorus	√	√
Potassium	√	√
Sodium	√	√
Total Protein	√	√
Total Protein 100	√	√
Triglycerides	√	√
Urea / Blood Urea Nitrogen	√	√
Uric acid	√	√
Format	Lyophilized human serum with chemical additives and materials of biological origin	
Stability	Closed stability: 30 months at 2-8°C Open stability: Once opened, the control components** are stable for : 12 hours at 15°C to 25°C 5 days at 2°C to 8°C	

ABX PENTRA P Control:	
	1 month at –25°C to –15°C .../... **Exceptions Direct Bilirubin 4 hours at 15°C to 25°C 8 hours at 2°C to 8°C 2 weeks at –25°C to –15°C Total Bilirubin 8 hours at 15°C to 25°C 1 day at 2°C to 8°C 2 weeks at –25°C to –15°C

ABX PENTRA Urine Control L/H:		
Analytes	Already cleared (K07249, K072115, K110137, K110530)	Included in this submission
Amylase	√	√
Calcium	√	√
New Calcium AS		√
Creatinine 120	√	√
Enzymatic Creatinine CP	√	√
Phosphorus	√	√
Glucose	√	√
Urea / Blood Urea Nitrogen	√	√
Uric acid	√	√
Urinary proteins	√	√
Format	Liquid solution prepared from human urine with chemical additives and materials of biological origin	
Stability	Closed stability: 2 years at 2-8°C Open stability: 30 days at 2-8°C	

Conclusions for Performance Testing:

The performance testing data conclude that the safety and effectiveness of the devices are not compromised, and that they met all acceptance criteria, demonstrating that the devices are substantially equivalent to their respective predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

July 3, 2013

Horiba ABX SAS
C/O Caroline Ferrer
Parc Euromédecine
Rue du Caducée - BP 7290
34184 Montpellier cedex 4
FRANCE

Re: K123171
Trade/Device Name: ABX PENTRA CALCIUM AS CP,
ABX PENTRA Multical,
ABX PENTRA N Control,
ABX PENTRA P Control,
ABX PENTRA Urine Control L/H
Regulation Number: 21 CFR 862.1145
Regulation Name: Calcium test system
Regulatory Class: II
Product Code: CJY, JIX, JJY
Dated: May 17, 2013
Received: May 20, 2013

Dear Ms. Ferrer:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical

device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Carol C. Benson -S for

Courtney H. Lias, Ph.D.
Director
Division of Chemistry and Toxicology Devices
Office of In Vitro Diagnostics
and Radiological Health
Center for Devices and Radiological Health

Enclosure

Indications for Use Form

510(k) Number (if known): k123171

Device Name: ABX Pentra Calcium AS CP

Indications for Use:

ABX Pentra Calcium AS CP reagent, with associated calibrator and controls, is a diagnostic reagent for quantitative in vitro determination of calcium in human serum, plasma and urine based on a colourimetric method, using the ABX Pentra 400 Clinical Chemistry analyzer. Measurement of calcium is used in the diagnosis and treatment of parathyroid disease, a variety of bone diseases, chronic renal disease and tetany (intermittent muscular contractions or spasms).

Prescription Use _X_____ And/Or Over the Counter Use ____.
(21 CFR Part 801 Subpart D) (21 CFR Part 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE; CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostics and Radiological Health (OIR)

Yung W. Chan -S

Division Sign-Off
Office of In Vitro Diagnostics and Radiological Health

510(k) k123171

Indication for Use Form

510(k) Number (if known): k123171

Device Name: ABX PENTRA Multical

Indications for Use:

The ABX PENTRA Multical is a calibrator for use in the calibration of quantitative Horiba Medical methods on Horiba Medical clinical chemistry analyzers.

Prescription Use _X_____ And/Or Over the Counter Use ____.
(21 CFR Part 801 Subpart D) (21 CFR Part 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE; CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostics and Radiological Health (OIR)

Yung W. Chan -S

Division Sign-Off
Office of In Vitro Diagnostics and Radiological Health

510(k)___k123171_____

Indication for Use Form

510(k) Number (if known): k123171

Device Name: ABX PENTRA N Control

Indications for Use:

The ABX PENTRA N Control is for use in quality control by monitoring accuracy and precision of Horiba Medical methods on Horiba Medical clinical chemistry analyzers.

Prescription Use _X_____ And/Or Over the Counter Use ____.
(21 CFR Part 801 Subpart D) (21 CFR Part 801 Subpart C)

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Yung W. Chan -S

Division Sign-Off
Office of In Vitro Diagnostics and Radiological Health

510(k)_k123171

Indication for Use Form

510(k) Number (if known): k123171

Device Name: ABX PENTRA P Control

Indications for Use:

The ABX PENTRA P Control is for use in quality control by monitoring accuracy and precision of Horiba Medical methods on Horiba Medical clinical chemistry analyzers.

Prescription Use _X_____ And/Or Over the Counter Use ____.
(21 CFR Part 801 Subpart D) (21 CFR Part 801 Subpart C)

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Concurrence of CDRH, Office of In Vitro Diagnostics and Radiological Health (OIR)

Yung W. Chan -S

Division Sign-Off
Office of In Vitro Diagnostics and Radiological Health

510(k)___k123171_____

Indication for Use Form

510(k) Number (if known): k123171

Device Name: ABX PENTRA Urine Control L/H

Indications for Use:

The ABX PENTRA Urine Control L/H is for use in quality control by monitoring accuracy and precision of Horiba Medical methods on Horiba Medical clinical chemistry analyzers.

Prescription Use __X____ (21 CFR Part 801 Subpart D)

And/Or

Over the Counter Use ____. (21 CFR Part 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE; CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostics and Radiological Health (OIR)

Yung W. Chan -S

Division Sign-Off
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510(k)___k123171_____